**DRAFT INSERT – 03/01**

PHARMACIA & UPJOHN COMPANY
CeeOn™ Edge Foldable Intraocular Lens
Model 911A

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

## DEVICE DESCRIPTION

CeeOn Edge foldable intraocular lenses are ultraviolet absorbing posterior chamber intraocular lenses. They are designed to be positioned posterior to the iris where the lens should replace the optical function of the natural crystalline lens. However, accommodation will not be replaced.

## INDICATIONS

CeeOn Edge foldable intraocular lenses are indicated for primary implantation for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed by phacoemulsification. The lens is intended to be placed in the capsular bag.

## PRECAUTIONS

Do not resterilize the lens as this can produce undesirable side effects.

Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.

Do not store the lens in direct sunlight or at a temperature greater than 50°C (122°F). Do not autoclave the intraocular lens.

Do not fold the lens across the loop anchors. The lens should not remain folded for more than 5 minutes.

## WARNINGS

Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:

1. Recurrent severe anterior or posterior segment inflammation or uveitis;
2. Patients in whom the intraocular lens may affect the ability to observe, diagnose or treat posterior segment diseases;

3. Surgical difficulties at the time of cataract extraction which may increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolapse or loss);
4. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible;
5. Circumstances that would result in damage to the endothelium during implantation;
6. Suspected microbial infection;
7. Patients in whom neither the posterior capsule nor the zonules are intact enough to provide support for the IOL;
8. Since the clinical study of CeeOn Edge lens Model 911A was conducted with the lens implanted in the capsular bag, there are insufficient clinical data to demonstrate the safety and efficacy for placement in the ciliary sulcus;
9. Small amounts of lens decentration occurring with an IOL having a narrow or small optic (<5.5mm) may cause glare or other visual disturbances under certain lighting conditions. Surgeons should consider this potential complication before implanting an IOL with a small or narrow optic.
10. Children under the age of 2 years are not suitable candidates for intraocular lenses.
11. The use of silicone oils in patients with current vitreoretinal disease or those who are at high risk for future vitreoretinal disease that may require silicone oil as part of therapy should be reconsidered.

**ADVERSE EVENTS**

The adverse events designated in the FDA "grid" which occurred during the clinical trial of Model 911A are shown in Table 1 below and are compared to the FDA "grid" values. Additional complications reported, in order of frequency, include the following: fibrosis, macular degeneration, posterior capsule opacification resulting in capsulotomy, Elschnig's pearls and diabetic retinopathy. Other complications that were not reported in the clinical trial but have been documented as occurring with the same type of intraocular lens include, but are not limited to, the following: flat anterior chamber, hyphema, vitreous in the anterior chamber, vitreous to wound, vitritis, anterior synechiae, posterior synechiae, non-constricting pupil, fibrin in pupil, cortical remnants, nuclear remnants, retinal detachment and optic atrophy.

Table 1
Adverse Events – One Year Postoperatively
Model 911A
N = 425 (Cumulative)
N = 326 (Persistent)

| Adverse Event | Model 911A (%) | FDA Grid (%) |
|---|---|---|
| Cumulative Hyphema | 0.0 | 1.0 |
| Cumulative Macular Edema | 3.8 | 3.5 |
| Cumulative Retinal Detachment | 0.0 | 0.5 |
| Cumulative Pupillary Block | 0.0 | 0.3 |
| Cumulative Lens Dislocation | 0.0 | 0.4 |
| Cumulative Endophthalmitis | 0.0 | < 0.1 |
| Cumulative Hypopyon | 0.0 | 0.4 |
| Cumulative Corneal Decompensation | 0.2 | 0.2 |
| Cumulative Surgical Reintervention<br>Lens repositioning<br>Wound leak repair<br>Focal laser therapy | 0.9<br>(0.2)<br>(0.2)<br>(0.5) | 2.0<br>--<br>-- |
| Persistent Cyclitic Membrane | 0.0 | < 0.1 |
| Persistent Vitritis | 0.0 | 0.1 |
| Persistent Macular Edema | 0.9 | 0.8 |
| Persistent Corneal Edema | 0.0 | 0.6 |
| Persistent Iritis | 0.0 | 1.0 |
| Persistent Raised IOP Requiring Treatment | 0.0 | 0.5 |

## CLINICAL TRIAL

A clinical trial of CeeOn Edge Model 911A was initiated on December 17, 1996. The results achieved by 320 patients followed for one year provide the basis for the data supporting the use of this IOL design for the visual correction of aphakia. In the total study population (425 patients), 58% of the patients were female, and 42% were male; 93% were Caucasian, 5% were Black, 2% were "Mixed" and 0.2% were designated as "Other". The Nd:YAG laser capsulotomy rate in the study population was 3.3% (14/425) at one year.

Table 2 provides the visual acuity results of the "best case" patients at 330-420 days postoperatively. "Best case" subjects are those patients with no preoperative pathology or macular degeneration at any time during the study. In addition, the data are compared to FDA "grid" values. (Table 3).

Table 2
"Best Case" Visual Acuity: 330-420 Days Postoperatively
CeeOn Edge Model 911A
N = 275

| Age | N | Best Corrected Visual Acuity – 330-420 Days | | | | | |
|---|---|---|---|---|---|---|---|
| | | 20/20 or Better | 20/21 to 20/40 | 20/41 to 20/80 | 20/81 to 20/100 | 20/101 to 20/200 | Worse Than 20/200 |
| < 60 | 11 | 5 (45%) | 6 (55%) | - | - | - | - |
| 60-69 | 73 | 46 (63%) | 27 (37%) | - | - | - | - |
| 70-79 | 139 | 71 (51%) | 66 (47%) | 2 (1%) | - | - | - |
| >79 | 52 | 19 (37%) | 32 (62%) | 1 (2%) | - | - | - |
| TOTAL | 275 | 141 (51%) | 131 (48%) | 3 (1%) | - | - | - |

Table 3
CeeOn Edge Model 911A vs. FDA "Grid"
Visual Acuity of "Best Case" Patients
N = 275 (Model 911A)

| Age | N | % of Patients With Visual Acuity of 20/40 or Better | |
|---|---|---|---|
| | | Model 911A | FDA "Grid" |
| <60 | 11 | 100% | 96.9% |
| 60-69 | 73 | 100% | 93.8% |
| 70-79 | 139 | 98% | 94.9% |
| >79 | 52 | 98% | 87.9% |
| Total | 275 | 99% | 94.0% |

**DETAILED DEVICE DESCRIPTION**

| | |
|---|---|
| Optic Material: | Silicone [161] |
| Power: | Available in 1.0 diopter increments from 5D to 10D; in 0.5D increments from 10.5D to 30D |
| Index of Refraction: | 1.46 |
| UV Transmittance: | 5 D Lens - UV cut-off at 10% is 391nm<br>30 D Lens - UV cut-off at 10% is 394nm |
| Loop Material: | Polyvinlyidene fluoride homopolymer (PVDF) |

Dimensions and loop shape of specific lens models are provided on the outside of the lens box, i.e., overall diameter, optic diameter, etc.

## SPECTRAL TRANSMITTANCE CURVE – Silicone [161]

(Curve will be the same as previously submitted.)

Legend:

Curve 1: Spectral transmittance (T) curve corresponding to the central region of a 5 diopter IOL, UV cut-off at 10% T is 391nm.

Curve 2: Spectral transmittance (T) curve corresponding to the central region of a 30 diopter IOL, UV cut-off at 10% T is 394nm.

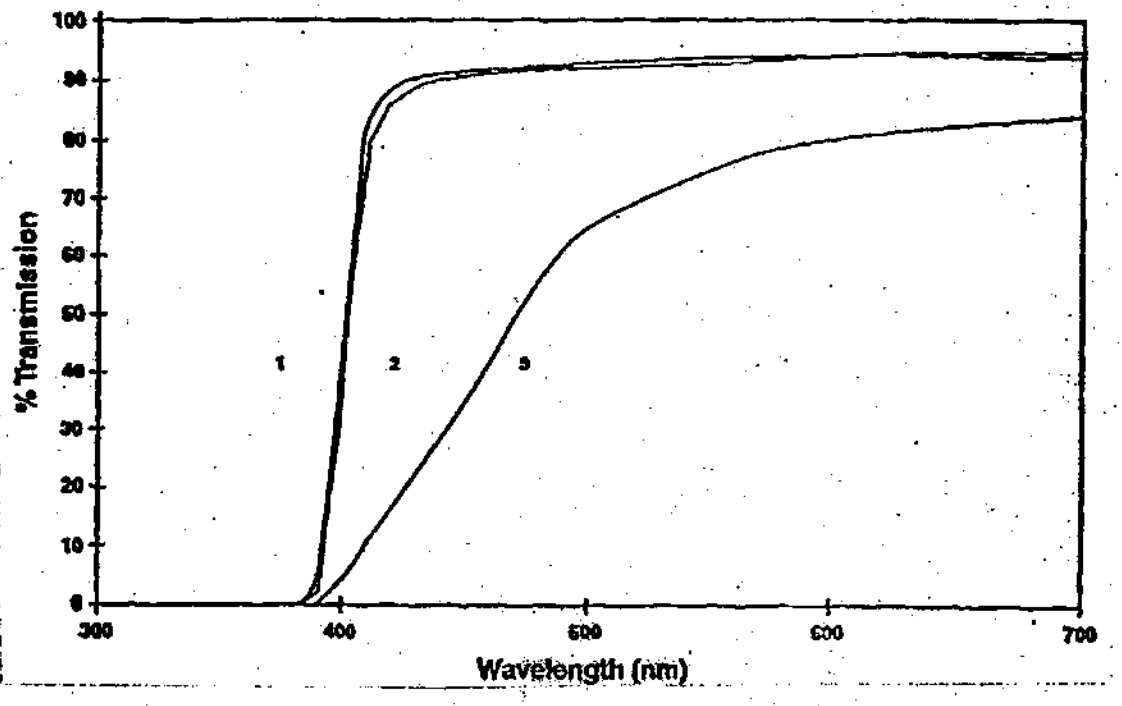
Curve 3: Spectral transmittance (T) curve corresponding to a 54-year-old phakic eye.

Reference: Boettner EA, Wolter JR. Transmission of the ocular media. *Investigative Ophthalmology*. 1:776-783, 1962.

## DIRECTIONS FOR USE

1. Prior to implanting, examine the lens package for type, power and proper configuration.
2. Open the peel pouch and remove the lens in a sterile environment.
3. Examine the lens thoroughly to ensure particles have not become attached to it, and examine the lens optical surfaces for other defects.
4. The lens may be soaked in sterile balanced salt solution until ready for implantation.
5. Use of any of the following folders is recommended: Fine II Folding Instrument (Rhein Medical P/N 8-01380); McDonald II Folding Instrument (Katena Products P/N K5-8237); Livernois McDonald II Folding Instrument (Katena Products P/N K5-8225); Ernest McDonald II Folding Instrument (Katena Products P/N K5-8228) and Faulkner Folding Instrument (Katena Products P/N K5-8231).

SPECTRAL TRANSMITTANCE CURVE – Silicone [161]



Caution: Do not use the lens if the package has been damaged. The sterility of the lens may have been compromised.

## LENS POWER CALCULATIONS

The physician should determine preoperatively the power of the lens to be implanted. Lens power calculation methods are described in the following references:


Hoffer KJ. The Hoffer Q formula: a comparison of theoretic and regression formulas. *J Cataract Refract Surg.* 19:700-712, 1993; ERRATA, 20:677, 1994.

Holladay JT, Musgrove KH, Prager TC, Lewis JW, Chandler TY and Ruiz RS. A three-part system for refining intraocular lens power calculations. *J Cataract Refract Surg.* 14:17-24, 1988.

Holladay JT. Standardizing constants for ultrasonic biometry, keratometry and intraocular lens power calculations. *J Cataract Refract Surg.* 23:1356-1370, 1997.

Norrby NES. Unfortunate discrepancies. Letter to the editor and reply by Holladay JT. *J Cataract Refract Surg.* 24:433-434, 1998.

Olsen T, Olesen H, Thim K and Corydon L. Prediction of pseudophakic anterior chamber depth with the newer IOL calculation formulas. *J Cataract Refract Surg.* 18:280-285, 1992.

Retzlaff JA, Sanders DR and Kraff MC. Development of the SRK/T intraocular lens implant power calculation formula. *J Cataract Refract Surg.* 16:333-340, 1990; ERRATA, 16:528, 1990.


Physicians requiring additional information on lens power calculations may contact Pharmacia & Upjohn Company at 1-800-423-4866.

## PATIENT REGISTRATION

The lens package contains product identification labels for maintaining a record of lens usage and patient registration. At the time of surgery, the postage-paid implant registration card (Lens Accountability Form) included in the package is to be completed and returned to Pharmacia & Upjohn Company where a record of all implants is maintained in order to monitor long-term effects of implantation of these lenses. ***FDA REQUIRES THAT REGISTRATION BE COMPLETED FOR ALL PATIENTS.***

An implant identification card, to be supplied to the patient, is also included in the package. The patient should be instructed to keep the card as a permanent record of his/her implant and to show the card to any eye care practitioner he/she may see in the future.

## REPORTING

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as lens-related and that were not previously expected in nature, severity or degree of incidence should be reported to Pharmacia & Upjohn Company at 1-800-423-4866. This information is being requested from all implant surgeons in order to document potential long-term effects of intraocular lens implantation.

## HOW SUPPLIED

Each CeeOn Edge UV light-absorbing silicone posterior chamber intraocular lens is supplied sterile, in dry form, in a lens container sealed within a single sterile pouch. The package is sterilized using ethylene oxide and should be opened only under sterile conditions.

## EXPIRATION DATE

The expiration date on the lens package is the sterility expiration date. The lens should not be implanted after the indicated sterility expiration date.

## RETURN / EXCHANGE POLICY

Contact Pharmacia & Upjohn Company at 1-800-423-4866 for the return lens policy. Return the lens with proper identification and the reason for the return. Label the return as a biohazard.

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Apple DJ, Federman JL, Krolicki TJ, Sims JC, Kent DG, Hamburger HA, Smiddy WE, Cox MSjr, Hassan TS, Compton SM, Thomas SG. Irreversible silicone oil adhesion to silicone intraocular lenses. A clinicopathologic analysis. *Ophthalmology.* 103(10):1555-1562, 1996.

Blaydes JE. Small incision intraocular lens: past, present and future. *Developments in Ophthalmology.* 18:107-110, 1989.

Brint SF, Ostrick DM, Bryan JE. Keratometric cylinder and visual performance following phacoemulsification and implantation with silicone small incision or polymethylmethacrylate intraocular lenses. *J Cataract Refract Surg.* 17(1):32-36, 1991.

Consultation section. Implanting silicone foldable lenses. *J Cataract Refract Surg.* 18(2):206-214, 1992.

Cornic JC, Pouliquen Y. First results with soft lens implants. *Developments in Ophthalmology.* 18:114-120, 1989.

Cumming JS. Postoperative complications and uncorrected acuities after implantation of plate haptic silicone and three-piece silicone intraocular lenses. *J Cataract Refract Surg.* 19(2):263-274, 1993.

Davison JA. Inflammatory sequelae with silicone and three-piece silicone intraocular lenses. *J Cataract Refract Surg.* 18(4):421-422, 1992.

Davison JA. Modified insertion technique of the SI-18NB intraocular lens. *J Cataract Refract Surg.* 17(6):849-853, 1991.

Gillis JP, Sanders DR. Use of small incisions to control induced astigmatism and inflammation following cataract surgery. *J Cataract Refract Surg.* 17 Suppl:740-744, 1991.

Guthoff R, Abramo F, Draeger J, Chumbley L. Measurement of elastic resisting forces of intraocular loops of varying geometrical designs and material composition. *J Cataract Refract Surg.* 16(5):551-558, 1990.

Hall DL. Silicone intraocular lens implants and circular anterior capsulotomy (capsulorhexis). *J of the Louisiana State Medical Society.* 141(2):20-21, 24-25, 1989.

Koch DD, Heat LE. Discoloration of silicone intraocular lenses. *Archives Ophthalmol.* 110(3):319-320, 1992.

Koch PS, Bradley H, Swenson N. Visual acuity recovery rates following cataract surgery and implantation of soft intraocular lenses. *J Cataract Refract Surg.* 17(2):143-147, 1991.

Legler UF, Apple DJ. Comments on silicone intraocular lens discoloration. *Archives Ophthalmol.* 109(11):1495-1496, 1991.

Martin RG, Sanders DR, VanderKarr MA, Deluca M. Effect of small incision intraocular lens surgery on postoperative inflammation and astigmatism. A study of the AMO SI-18NB small incision lens. *J Cataract Refract Surg.* 18(1):51-57, 1992.

Neuman AC, Cobb B. Advantages and limitations of current soft intraocular lenses. *J Cataract Refract Surg.* 15(3):257-263, 1989.

Nimoy M. Silicone intraocular lens implant discoloration in humans. *Archives Ophthalmol.* 109(8):1057, 1991.

Oh KT. Simplified insertion technique for the SI-18NB intraocular lens. *J Cataract Refract Surg.* 18(6):619-622, 1992.

Shepard JR. Capsular opacification associated with silicone implants. *J Cataract Refract Surg.* 15(4):448-450, 1989.

Shepard JR. Continuous tear capsulotomy and insertion of a silicone bag lens. *J Cataract Refract Surg.* 15(3):335-339, 1989.

Shimizu K, Komatsu M. Physical fixation of soft intraocular lenses. *J Cataract Refract Surg.* 15(5):580-583, 1989.

Watt RH. Discoloration of a silicone intraocular lens 6 weeks after surgery. *Archives Ophthalmol.* 109(11):1494-1495, 1991.

Wolter JR, Sugar A. Refractive membrane on a foldable silicone lens implant in the posterior chamber of a human eye. *Ophthalmic Surgery.* 20(1):17-20, 1989.

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